

Application No. 09/711,648

The amendments find full support in the original specification, claims and drawings. No new matter is presented.

The Examiner rejected claims 1 to 12 under 35 U.S.C. § 102(b) as allegedly anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as allegedly obvious over, U.S. Patent No. 5,370,675 to Edwards ("Edwards '675"). Additionally, the Examiner rejected claims 13 to 20 under 35 U.S.C. § 103(a) as allegedly unpatentable over Edwards '675 in view of U.S. Patent No. 5,599,294 to Edwards ("Edwards '294"). Applicant respectfully traverses these rejections.

Original independent claims 1 and 9, as well as new independent claim 23, are directed to an injection catheter. Claim 1 recites that the injection catheter includes an injection needle extending through the tip section, catheter body, and needle control handle and having a proximal end attached to the needle control handle and a distal end within the tip section, wherein the injection needle is longitudinally slidable within the tip section so that its distal end can extend out the distal end of the catheter upon suitable manipulation of the needle control handle. Claims 9 and 23 contain similar limitations. This design is neither taught nor suggested by either of the Edwards patents.

The Edwards patents are both directed to a probe device that is particularly useful for treating benign prostatic hypertrophy or hyperplasia (BPH). Although Edwards '294 states that the device can be used to destroy body tissues in areas other than the prostate such as the heart, Edwards' device is designed to be useful for treating the prostate. In view of this purpose, Edwards' device includes a stylet guide housing with a stylet port in a side wall thereof and a flexible stylet that can be guided outward through the stylet port at a preselected angle to a target tissue. (See Edwards '675 at column 3, lines 42 to 47.) As shown in Figure 4, the stylet guide housing 50 is mounted coaxially on the distal end of the catheter 48. The stylet 54 comprises a solid core needle 56 coaxially positioned and longitudinally moveable within a tube 58. The guide housing 50 has a guide channel 61 that is curved to permit longitudinal advancement of the stylet 54. (See Edwards '675, column 10, lines 1 to 14.) In all of the embodiments of both of the Edwards patents, the stylet port is in the sidewall of the stylet guide housing so that the stylet extends out of the side of the stylet guide housing at an angle relative to the guide housing and catheter body.

Nothing in Edwards teaches or suggests that the needle is longitudinally slidable within the tip section so that its distal end can extend out the distal end of the catheter, as presently claimed. Applicant recognizes that Edwards '675 states at column 14, lines 53 to 60:

The embodiment shown in FIGs. 15 and 16 comprises two sets of stylets, each pair extending from ports in a common plane perpendicular to the catheter central axis. It will be readily apparent to a person skilled in the art that other stylet arrays such as a longitudinal array or a spiral array can also be used, and these variations are considered to be fully within the scope of this invention.

The references to a "longitudinal array" and a "spiral array" in this passage are not describing the stylet extending out the distal end of the catheter. Instead they refer to the fact that the stylets extending out the stylet ports in the sidewalls of the guide housing can be arranged in an array whereby the stylets extend longitudinally or in a spiral relative to the catheter central axis rather than perpendicular to the catheter axis. In other words, the stylets bend or curve after they extend out of the stylet ports in the sidewalls. If this passage were read otherwise, such embodiments would not be within the scope of the claimed invention, as all of the claims of Edwards '675 recite a "stylet guide means disposed in the stylet guide housing for retaining and directing the stylet outward through a stylet port in a side of the stylet guide housing." (Edwards '675, column 19, lines 25 to 28, emphasis added.)

Because neither Edwards patent teaches a needle that is longitudinally slidable within the tip section so that its distal end can extend out the distal end of the catheter, as presently claimed, neither Edwards patent anticipates the present claims. Moreover, neither Edwards patent suggests such a design. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." M.P.E.P. § 2143.01. In the present case, neither Edwards patent suggests the desirability of the modification that would have to be made to arrive at the claimed invention. Instead, both Edwards patents emphasize that the stylet extends out the sidewall of the guide housing. Accordingly, the Edwards patents, alone or in combination, do not anticipate or render obvious the claimed invention. Applicant therefore respectfully requests that the rejections over the Edwards patents be withdrawn.

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In view of the foregoing amendments and remarks, Applicant submits that pending claims 1 to 29 are in condition for allowance, and a timely indication of allowance is respectfully requested. If there are any remaining issues that can be addressed by telephone, Applicant invites the Examiner to contact the undersigned at the number indicated below.

Respectfully submitted,

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KMO/edb

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims:

Please amend claims 1 and 9 as follows:

1. (Amended) An injection catheter comprising:

• a catheter body comprising a flexible tubing having proximal and distal ends and at least one lumen therethrough;

a tip section comprising a flexible tubing having proximal and distal ends, wherein the proximal end of the tip section is mounted at the distal end of the catheter body;

a needle control handle at the proximal end of the catheter body;

an injection needle extending through the tip section, catheter body, and needle control handle and having a proximal end attached to the needle control handle and a distal end within the tip section, wherein the injection needle is longitudinally slidable within the tip section so that its distal end can extend [~~beyond~~] out the distal end of the [~~tip section~~] catheter upon suitable manipulation of the needle control handle; and

an electrode lead wire having a first end electrically connected to the injection needle and a second end electrically connected to a suitable monitoring apparatus or to a source of ablation energy.

9. (Amended) An injection catheter comprising:

• a catheter body comprising a flexible tubing having proximal and distal ends and at least one lumen therethrough;

a tip section comprising a flexible tubing having proximal and distal ends, wherein the proximal end of the tip section is mounted at the distal end of the catheter body;

a needle control handle at the proximal end of the catheter body;

an injection needle extending through the tip section, catheter body, and needle control handle and having a proximal end attached to the needle control handle and a distal end within the tip section, wherein the injection needle is longitudinally slidable within the tip section so

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that its distal end can extend ~~[beyond]~~ out the distal end of the ~~[tip-section]~~ catheter upon suitable manipulation of the needle control handle;

an electrode mounted on the injection needle near the distal end of the injection needle and electrically isolated from the injection needle;

an electrode lead wire having a first end electrically connected to the electrode and a second end electrically connected to a suitable monitoring apparatus or to a source of ablation energy.

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